DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
BUFFALO MN 55313

Re: K141846
Trade/Device Name: Acuson X700™ and Acuson X600™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: July 8, 2014
Received: July 9, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson X700 and Acuson X600 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1	AcuNav 10F	C6F2
VF10-5	V5Ms	C8F3
VF12-4	4V1c	EV9F3
EC9-4w	C7F2	C8-5
6C2	EV9F4	P8-4
CW2	SoundStar 10F	MC9-4
CW5	SoundStar eco 10F	CH5-2
AcuNav 8F	VF16-5	C6-2
SoundStar eco 8F		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141846

Device Name: ACUSON X700™ and X600 ™ Diagnostic Ultrasound System

Indications For Use:

The Siemens ACUSON X700™ and X600 ™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav and Soundstar Ultrsound Catheter are intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Type of Use (Select one or both, as applicable)

_X_ Prescription Use (21 CFG 801 Subpart D) ___Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **ACUSON X700 Diagnostic Ultrasound Systems**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12,19,21
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11,12,20,22
	Intra-operative (Note 6)	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Neuro)								Note 2,3,4,5,6,9,10
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	SmallOrgan (Note 1)	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11,19, 22
	Neonatal Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Adult Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,19
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12,19,21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,11,22
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11,22
	Intra -vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,8,9, 13,14,15,16,17,18,19
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,8,9,10,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Intra-Cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **ACUSON X600 Diagnostic Ultrasound Systems**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11,12,20
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	SmallOrgan (Note 1)	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11,19
	Neonatal Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Adult Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,19
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12,19
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra -vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,8,9, 13,14,15,16,17,18,19
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,8,9,10,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **4C1** Curved Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10, 20
	Intra-operative (Note 6)	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **VF10-5** Linear Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11,22
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Adult Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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510(k) K141846

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **VF12-4** Linear Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-operative (Note 6)								
	Intra-operative (Neuro)						-		
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11,22
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Adult Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **EC9-4w** Convex Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12, 21
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12, 21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
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Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **6C2** Curved Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Note 6)	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **CW2** Continuous Wave Doppler Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal				P				
	Abdominal				P				
	Intra-operative (Note 6)				P				
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				P				
	SmallOrgan (Note 1)				P				
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel				P				
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **CW5** Continuous Wave Doppler Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal				P				
	Abdominal				P				
	Intra-operative (Note 6)				P				
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				P				
	SmallOrgan (Note 1)				P				
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel				P				
Vessel	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **AcuNav 8F** Intracardiac Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **AcuNav 10F** Intracardiac Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **V5Ms** TEE Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **4V1c** Phased Sector Array Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound System

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,9
	Abdominal	P	P	P		P	P	BMDC	Note 2,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic	P	P	P	P	P	P	BMDC	Note 2,9
	Adult Cephalic	P	P	P	P	P	P	BMDC	Note 2,9
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,8,9, 13, 14
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **C7F2** Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1l& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **EV9F4** Curved Array Mechanical 3D/4D Transducer for use with: **ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12, 19,
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,19
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12,19, 21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **SoundStar 10F** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **SoundStar eco 10F** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **VF16-5** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11,22
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N		Note 2,3,4,9,10,11
	SmallOrgan (Note 1)	N	N	N		N	N		Note 2,3,4,9,10,11,22
	Neonatal Cephalic	N	N	N		N	N		Note 2,3,4,9,10,11
	Adult Cephalic	N	N	N		N	N		Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N		Note 2,3,4,9,10,11,22
	Musculo-skel. (Superfic)	N	N	N		N	N		Note 2,3,4,9,10,11,22
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N		Note 2,3,4,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **C6F2** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
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Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **C8F3** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,6,9,10
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
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Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **EV9F3** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems / ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,19
	Trans-vaginal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,19,21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
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Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
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Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **C8-5** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Note 6)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Neuro)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Adult Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
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Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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510(k) K141846

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **P8-4** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Note 6)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Neuro)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Adult Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **MC9-4** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,21
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Trans-vaginal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12,21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **CH5-2** Transducer for use with:
ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Note 6)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **C6-2** Transducer for use with:
ACUSON X600 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Note 6)	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging
Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSinght 4D imaging
Note 20 Contrast Agent Imaging
Note 21 syngo Auto follicle (X700 only)
Note 22 eSie Touch (X700 only)

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) K141846

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K141846

Device Name: **Soundstar eco 8F** Transducer for use with:
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**							
Other (Track1 Only)	Specific (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Cardiac Pediatric	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) K141846

510(k) Summary
Prepared June 25, 2014

Sponsor: Siemens Medical Solutions, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Manufacturing Facility
SIEMENS LTD SEOUL
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Device Name: ACUSON X700™ Ultrasound System
ACUSON X600™ Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code OBJ

A. Legally Marketed Predicate Devices

The Siemens ACUSON X700™ and X600™ Ultrasound Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens ACUSON X700 ultrasound system (K123001), ACUSON S2000 ultrasound system (K112596), X300 ultrasound system (K121699), S1000/S2000/S3000 ultrasound systems (K132804)

B. Device Description:

The Siemens ACUSON X700™ and X600™ are multi-purpose mobile, software controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Tissue Doppler Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

C. Intended Use

The Siemens ACUSON X700™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The ACUSON Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients

D. Substantial Equivalence

The Siemens ACUSON X700™ and X600™ Ultrasound Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens ACUSON X700 ultrasound system (K123001), ACUSON S2000 ultrasound system (K112596), X300 ultrasound system (K121699), S1000/S2000/S3000 ultrasound systems (K132804). All systems transmit ultrasonic energy into patients, and then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

Feature / Characteristic	Predicate Device ACUSON X700 (K123001)	Predicate Device ACUSON S2000 (K112596)	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S1000/S2000/3000 (K132804)	Submission Device ACUSON X600™	Submission Device ACUSON X700™
Indications for Use:						
▪ Fetal Echo	√	√	√	√	√	√
▪ Abdominal	√	√	√	√	√	√
▪ Renal	√	√	√	√	√	√
▪ Cerebrovascular	√	√	√	√	√	√
▪ Orthopedics	√	√	√	√	√	√
▪ Small Organ	√	√	√	√	√	√

Feature / Characteristic	Predicate Device ACUSON X700 (K123001)	Predicate Device ACUSON S2000 (K112596)	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S1000/S2000/3000 (K132804)	Submission Device ACUSON X600™	Submission Device ACUSON X700™
▪ Pediatric	√	√	√	√	√	√
▪ Adult Cephalic	√	√	√	√	√	√
▪ Cardiac (Adult)	√	√	√	√	√	√
▪ Intracardiac	√	√	√	√	√	√
▪ Trans-esophageal	√	√	√	√	√	√
▪ Transrectal	√	√	√	√	√	√
▪ Urolology	√	√	√	√	√	√
▪ Transvaginal	√	√	√	√	√	√
▪ Peripheral vessel	√	√	√	√	√	√
▪ Musculo-skeletal (conventional)	√	√	√	√	√	√
▪ Musculo-skeletal (superficial)	√	√	√	√	√	√
▪ Emergency Medicine	√	√	√	√	√	√
Center Frequencies Supported:						
▪ 2.0 MHz	√	√	√	√	√	√
▪ 2.5 MHz	√	√	√	√	√	√
▪ 3.0 MHz	√	√	√	√	√	√
▪ 3.5 MHz	√	√	√	√	√	√
▪ 4.0 MHz	√	√	√	√	√	√
▪ 5.0 MHz	√	√	√	√	√	√
▪ 5.5 MHz	√	√	√	√	√	√
▪ 6.0 MHz	√	√	√	√	√	√
▪ 6.5 MHz	√	√	√	√	√	√
▪ 7.5 MHz	√	√	√	√	√	√
▪ 8.0 MHz	√	√	√	√	√	√
▪ 9.0 MHz	√	√	√	√	√	√
▪ 10.0 MHz	√	√	√	√	√	√
▪ 11.0 MHz	√	√	√	√	√	√
▪ 12.0 MHz	-	-	-	-	-	√
▪ 13.0 MHz	-	-	-	-	-	√
Modes:						
▪ B	√	√	√	√	√	√
▪ M	√	√	√	√	√	√
▪ PWD (Pulsed Wave Doppler)	√	√	√	√	√	√
▪ CWD (Continuous Wave Doppler)	√	√	√	√	√	√
▪ SCW (Steerable CW)	√	√	√	√	√	√
▪ CD (Color Doppler)	√	√	√	√	√	√
▪ Amplitude Doppler (Power Doppler)	√	√	√	√	√	√

Feature / Characteristic	Predicate Device ACUSON X700 (K123001)	Predicate Device ACUSON S2000 (K112596)	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S1000/S2000/3000 (K132804)	Submission Device ACUSON X600™	Submission Device ACUSON X700™
▪ Directional Power Doppler	√	√	√	√	√	√
▪ Combined (BM, BC, BCM, BCD)	√	√	√	√	√	√
▪ THI (Tissue Harmonic Imaging)	√	√	√	√	√	√
▪ AMM (Anatomical M-mode)	√	√	√	√	√	√
▪ Doppler Tissue Image (Color, PW)	√	√	√	√	√	√
▪ M-THI	√	√	√	√	√	√
Features:						
▪ Multi-View Spatial Compounding (SieClear)	√	√	√	√	√	√
▪ Advanced SieClear	√	√	-	√	√	√
▪ DTCE (Dynamic Tissue Contrast Enhancement)	√	√	√	√	√	√
▪ Tissue Grayscale Optimization (TGO)	√	√	√	√	√	√
▪ Dual-Beam Processing	√	√	√	√	√	√
▪ Quad-Beam Processing	√	√	√	√	√	√
▪ Clip Capture	√	√	√	√	√	√
▪ 3D Imaging (3-Scape)	√	√	√	√	√	√
▪ 3D Measurements	√	√	√	√	√	√
▪ 4D Basic Imaging (fourSight 4D)	√	√	√	√	√	√
▪ Panoramic 2D Imaging (SieScape)	√	√	√	√	√	√
▪ Syngo Auto OB	√	√	√	√	√	√
▪ Syngo Auto Follicle	√	-	-	-	-	√
▪ Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging	√	√	√	√	√	√
▪ Stress Echo	√	√	√	√	√	√
▪ Vascular Enhancement (Clarify VE)	√	√	√	√	√	√

Feature / Characteristic	Predicate Device ACUSON X700 (K123001)	Predicate Device ACUSON S2000 (K112596)	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S1000/S2000/3000 (K132804)	Submission Device ACUSON X600™	Submission Device ACUSON X700™
▪ Syngo VVI (Velocity Vector Image)	√	√	√	√	√	√
▪ Auto Left Heart	√	√	√	√	√	√
▪ Axius EF	√	√	√	√	√	√
▪ Syngo AHP	√	√	√	√	√	√
▪ Contrast Agent Image	√	√	√	√	√	√
▪ DIMAQ	√	√	√	√	√	√
▪ Multiple Frequency Imaging(MultiHertz)	√	√	√	√	√	√
▪ syngo Mitral Valve Assessments (MVA)	√	√	√	√	√	√
▪ Intracardiac Echocardiography (ICE) Imaging	√	√	√	√	√	√
▪ Digital Architecture	√	√	√	√	√	√
▪ Panoramic 2D Imaging (Siescape)	√	√	√	√	√	√
▪ Fully integrated DICOM	√	√	√	√	√	√
▪ CARTOSOUND ™ Communication	√	-	√	√	-	√
▪ Monitor: 20” wide (FPD)	√	**√ (19” FPD)**	**(17” FPD)**	**√ (21” FPD)**	√	√
▪ Wireless	√		√	√	√	√
▪ eSie Touch	-	√	-	√	-	√
# Channels	**128**	**192**	**128**	**192**	**128**	**128**
Output Display Standard (Track 3)	√	√	√	√	√	√
Patient Contact Materials	**Tested to ISO 10993-1**	**Tested to ISO 10993-1**	**Tested to ISO 10993-1**	**Tested to ISO 10993-1**	**Tested to ISO 10993-1**	**Tested to ISO 10993-1**
UL60601-1 Certified	√	√	√	√	√	√

E. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
  - EN/IEC 62304
  - EN/IEC 62366
  - EN/IEC 60601-2-18
  - EN/IEC 60601-2-25
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

F. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the ACUSON X700 and X600 use the same technology and principles as existing devices, clinical data is not required.

G. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the ACUSON X700 and X600 are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON X700 and X600 are verified and validated according to the company's design control process.